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Food and Drug Administration

[Docket No. FDA-2022-N-2855]

Mylan Institutional, Inc.; Withdrawal of Approval of a New Drug Application for SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of new drug application (NDA) 019832 for SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution, held by Mylan Institutional, Inc., a Viatris company (Mylan). Mylan has voluntarily requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Applicable [insert date of publication in the *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6262, Silver Spring, MD 20993, 301-796-3601.

SUPPLEMENTARY INFORMATION: On June 5, 1998, the Food and Drug Administration (FDA) approved NDA 019832 for SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution, under the Agency's accelerated approval regulations (see generally 21 CFR subpart H). It was approved for "for use as an adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds."

NDA 019832's accelerated approval was "subject to the requirement that the applicant study the drug further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome" (21 CFR 314.510). To date, however, Mylan has not completed the required confirmatory study. Mylan acknowledged in its December 10, 2021, letter requesting

withdrawal of approval that a successful confirmatory study was necessary to fulfill the accelerated approval requirements, but stated that conducting such a study is not feasible. Mylan thus requested that NDA 019832 be withdrawn under 21 CFR 314.150(d), and waived its right to a hearing.

Thus, for the reasons discussed above, under 21 CFR 314.150(d), approval of NDA 019832 for SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution, and all amendments and supplements thereto, is withdrawn. Distribution of SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: November 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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